

Application No. 10/748,432  
Amdt. dated June 17, 2005  
Reply to Office action of March 17, 2005

### **REMARKS/ARGUMENTS**

Claims 15-36 are under examination in the application. The Office Action mailed on March 17, 2005, includes the following objections and rejections:

1. Claim 15-36 is rejected under Double Patenting
2. Claim 15-36 is rejected under 35 U.S.C. § 112, first paragraph.

Applicant respectfully addresses the basis for each of the Examiner's rejections below.

***Claim Rejections – Claims 15-36 are rejected under 35 U.S.C. § 112, First paragraph***

The Action rejects Claims 15-36 under 35 U.S.C. § 112 1st paragraph, as failing to comply with the written description requirement. The Federal Circuit has held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." See, e.g., *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. See, e.g., *In re Wands*. The Action must address each of these factors, all the evidence related to each factors, and any conclusion must be based on the evidence as a whole. Applicant submits that the subject matter of the claims is described in the specification in such a way as to reasonably convey to one skilled in the relevant art, that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant submits that the present disclosure enables those skilled in the art to make and use the full scope of the claimed invention without undue experimentation. For example, the specification provides detailed examples using a seven carbon fatty acid and states that substituted, unsaturated or branched heptanoates can be used in addition to other modified seven-carbon fatty acids. The present specification provided considerable direction and guidance on how to practice the claimed invention and presented working examples, and all of the methods needed to practice the invention were either well known in the art or disclosed in the specification. Applicant asserts that when the factors to determine undue experimentation set forth in *In re Wands* are addressed in their entirety the claimed invention is enabled so that any person skilled in the art can make and use the invention without undue experimentation.

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Applicant addresses the *In re Wands* factors in turn.

With regard to the breadth of the claims, the claims are not overly broad as the specification only includes a select group of fatty acids (e.g., to seven carbon fatty acids) as opposed to all fatty acids or different groups containing fatty acids of vastly different numbers of carbons. For example, the seven carbon fatty acids are a group of fatty acids with similar chemical properties as a group, e.g., found mainly in milk fats, have similar physical properties and interactions and so forth. Although, the fatty acid may be modified, such modifications are known to persons of ordinary skill in the art. The specification teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

With regard to the quantity of experimentation necessary, the present invention does not require complicated assays and all necessary information is present in the direction and guidance of the specifications or known to a person of skill in the art.

With regard to the level of predictability in the art, the predictability in the art is high as much is known of fatty acid chemistry and characteristics and the modification and substitution of fatty acids. As the group contains similar properties, number of carbons, characteristics the specification teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

With regard to the level of one of ordinary skill, the level of skill in the art is high as the field is populated with Doctors, both PhD and MD, as well as post doctoral researcher.

With regard to the amount of direction provided by the inventor, quantity of experimentation needed to make or use the invention based on the content of the disclosure and the existence of working examples, the specification provides direction and guidance as well as a representative example of the seven carbon fatty acid chain and the derivatives thereof. The study of fatty acids has been around for decades; and as such, much is known in the art regarding there properties, reactions and modification. The specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, thus satisfying the enablement requirement. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Furthermore, it is not necessary for the specification to provide every modification and

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configuration, See, e.g., *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) (As not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further, the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

As such, the specification satisfies the written description requirement under 35 U.S.C. § 112, first paragraph. For the reasons mentioned above, the Applicant respectfully requests the Examiner withdraw the rejection under 35 U.S.C. § 112.

***Claim Rejections – Claims 15-36 under the nonstatutory Doctrine of Double Patenting***

The Examiner provisionally rejected claims 15-36 under the nonstatutory, judicially created Doctrine of Double Patenting over claims 25-40 of copending Application No. 10/371,685.

The Examiner states the subject matter claimed in the instant application provisionally rejected over the copending Application No. 10/371,685 is covered by the patent since the patent and the application are claiming common subject matter.

A terminal disclaimer in compliance with 37 CFR 1.321(c) will be filed as necessary to overcome the rejection based on a nonstatutory double patenting ground provided the conflicting patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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**Conclusion**

In light of the remarks and arguments presented above, Applicant respectfully submits that the claims in the Application are in condition for allowance. Favorable consideration and allowance of the pending Claims 15-36 are therefore respectfully requested.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: June 17, 2005.

Respectfully submitted,



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